EXHIBIT A

Case Information

LAWSON VS BIOMET INC

23-C-05517-S7

Location	Case Category	Case Type	Case Filed Date
Gwinnett County - State Court - Division 7	Civil	Tort - Product Liability Tort*	8/3/2023

Judge	Case Status
Smith, Jaletta L.	Open (Pending)

Parties 2

Type	Name	Nickname/Alias	Attorneys
Plaintiff	AUDREY LAWSON		ADAM M COLLINS, TIMOTHY K HALL
Defendant	BIOMET INC		Pro Se

Events 4

Date	Event	Type	Comments	Documents
8/3/2023	Filing	Summons		Summons.pdf
8/3/2023	Filing	Complaint with Jury Demand		Complaint.pdf
8/3/2023	Filing	Request for Production		Pl.'s 1st RPDs to Def.pdf
8/3/2023	Filing	Interrogatories		Pl.'s 1st ROGs to Def.pdf

Version: 2023.8.0.52

E-FILED IN OFFICE - NN
CLERK OF STATE COURT
GWINNETT COUNTY, GEORGIA
23-C-05517-S7
8/3/2023 3:59 PM
TIANA P. GARNER, CLERK

IN THE STATE COURT OF GWINNETT COUNTY

STATE OF GEORGIA

Audrey Lawson

CIVIL ACTION NUMBER: **23C-05517-S7**

PLAINTIFF

VS.

Biomet, Inc. d/b/a Zimmer Biomet

DEFENDANT

SUMMONS

TO THE ABOVE NAMED DEFENDANT:

You are hereby summoned and required to file with the Clerk of said court and serve upon the Plaintiff's attorney, whose name and address is:

Hall & Collins Injury Law, LLC
594 Oconee St., Suite 111
Athens, GA 30605

an answer to the complaint which is herewith served upon you, within 30 days after service of this summons upon you, exclusive of the day of service. If you fail to do so, judgment by default will be taken against you for the relief demanded in the complaint.

This 3 **day of** August, **20**23.

Tiana P. Garner
Clerk of State Court

By Nichole Norton
Deputy Clerk

INSTRUCTIONS: Attach addendum sheet for additional parties if needed, make notation on this sheet if addendum sheet is used.

SC-1 Rev. 2011

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CLERK OF STATE COURT
GWINNETT COUNTY, GEORGIA
23-C-05517-S7
8/3/2023 2:46 PM
TIANA P. GARNER, CLERK

IN THE STATE COURT OF GWINNETT COUNTY
STATE OF GEORGIA

AUDREY LAWSON, Plaintiff, v. **BIOMET, INC.** d/b/a Zimmer Biomet, Defendant.	**CIVIL ACTION NO.** 23-C-05517-S7

COMPLAINT

COMES NOW, Audrey Lawson, Plaintiff in the above-captioned civil action, and files this Complaint against the named Defendant Biomet, Inc. d/b/a Zimmer Biomet and respectfully shows the Court as follows:

Introduction

1.

This is a personal injury/products liability lawsuit arising from a defective knee implant device designed, manufactured, and sold by the above-referenced Defendant. The defective device is known as a Regenerex Series A Patella. On March 22, 2017, Defendants issued a recall of all Regenerex Series A Patellas because the rate at which the patella pegs would "shear off" after surgery was higher than Defendant's expectations and experience with other similar devices. In fact, the average time for the peg "shearing" to occur was only about 18 months.

2.

Ms. Audrey Lawson underwent a total knee replacement surgery on November 10, 2015, and had a defective Regenerex Series A Patella installed in her right knee. After having pain and issues with her revised knee, it was determined that Ms. Lawson right knee implant had failed.

3.

On November 16, 2020, Ms. Lawson underwent a revision surgery to replace the defective implant. During the revision surgery, her surgeon found "a lot of scar tissue underneath the patella" and that "[o]nce the patella was removed, the 3-peg was all broken off and remained in the patella."

4.

The defective and recalled implant caused Ms. Lawson to require at least five (5) additional surgeries, and she further contracted a severe infection in her knee. This includes but is not limited to the following operations:

- right knee patella realignment;
- right knee irrigation & wound vac placement;
- right knee hardware removal surgery & insertion of concrete spacer; and
- a right ankle surgery.

As of the date of this Complaint, Ms. Lawson is waiting to get her right knee hardware reinserted.

5.

Pursuant to Georgia state law, Ms. Lawson brings this personal injury and products liability lawsuit against the Defendant seeking a remedy for the damages suffered by her due to Defendant's failed, defective, and recalled knee implant.

6.

The parties have previously entered an agreement tolling the statute of limitations to at least September 30, 2023.

Parties, Jurisdiction, and Venue

7.

Plaintiff is a Georgia resident.

8.

Defendant Biomet, Inc. d/b/a Zimmer Biomet (hereafter, referred to as Zimmer Biomet or Defendant) is an Indiana corporation with a registered office and registered agent at the following address:

Corporation Service Company
135 North Pennsylvania, Suite 1610,
Indianapolis, IN 46204

9.

Upon information and belief, Zimmer Biomet is an incorporation that designs, creates, manufactures, tests, labels, packages, supplies, sells, markets, advertises, and distributes medical devices to residents of Georgia, including but not limited to the Vanguard Complete Knee System and the Regenerex Series A Patella products.

10.

Zimmer Biomet, or by and through their subsidiaries, derive substantial revenues from business in Georgia.

11.

Zimmer Biomet is subject to the jurisdiction and venue of this Court. See generally, O.C.G.A. §§ 9-10-90, 9-10-91, 9-10-93, 14-8-46, 14-2-510, 9-10-31; Ga. Const. Art. VI, Sec. II, Para. IV; Ga. Const. Art. VI, Sec. II, Para. VI; and *Colt Indus. & C. v. Coleman,* 246 Ga. 559, 560 (1980).

General Allegations

12.

Around 2012, Plaintiff Audrey Lawson (hereafter, "Ms. Lawson") started to experience persistent right knee pain. Ms. Lawson went to Excel Orthopaedics and started treating with orthopedic surgeon – Dr. Jeff Traub (hereafter, "Dr. Traub").

13.

Dr. Traub diagnosed Ms. Lawson with right knee osteoarthritis and after three (3) years of treatment and several right knee injections, Dr. Traub finally recommended Ms. Lawson undergo a total right knee arthroplasty.

14.

As part of his recommendation to Ms. Lawson to undergo a right knee arthroplasty, Dr. Traub recommended that Ms. Lawson have implanted a Vanguard Knee System (hereafter, the "Vanguard Knee Implant").

15.

The Vanguard Knee Implant recommended by Dr. Traub for Ms. Lawson's right knee replacement surgery included the use of a Regenerex® 3 Peg, Series A Patella that was designed, created, manufactured, tested, labeled, packaged, supplied, sold, marketed, advertised, and distributed by Defendant, specifically: BIOMET REF. # 141356, LOT # 870260, Series A Patella 3 Peg, DCM ArCom, Porious Titanium 31mm (hereafter, the "Regenerex® 3-Peg Patella Implant").

16.

The Regenerex® 3-Peg Patella Implant was designed, created, manufactured, tested,

labeled, packaged, supplied, sold, marketed, advertised, and distributed by Defendant to treat knee osteoarthritis and to be used in total knee arthroplasty operations.

17.

The 3-Peg Patella Implant was designed by Defendant with two pieces: (1) a semi-circular polyethylene dome on one side, and (2) a Regenerex® Porous Titanium Construct on the other side with three (3) porous peg legs meant to attach to the back of the patella bone.

18.

Defendant designed and intended for the surgeon to cut the patella bone and drill three (3) holes for the three (3) porous peg legs to fit into the bone. Defendant designed and intended for the bone to grow into the Regenerex® Porous Titanium Construct and create a tight and lasting bond.

19.

If the Vanguard Knee Implant is to perform as designed and intended, the porous peg legs located on the Regenerex® 3-Peg Patella Implant must remain fixed and attached to polyethylene liner. If the porous metal legs were to become unattached or break while inside a person's body, it could result in a failure of the knee implant.

20.

Such failure described above could cause serious injury to the patient, including the need for one or more additional surgeries to remove the failed implant. Such additional surgeries increase the risk for the patient to get an infection.

21.

Defendant Zimmer Biomet represented and warranted that the Regenerex® 3-Peg Patella

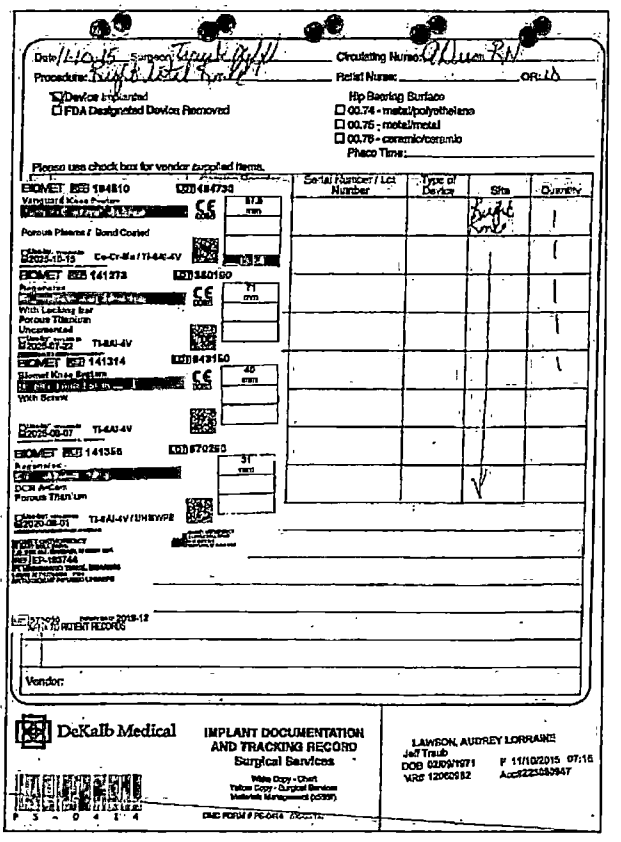
Implant was a safe product and fit for use in a total knee arthroplasty.

22.

On November 10, 2015, Dr. Traub -- an orthopedic surgeon -- performed a total right knee arthroplasty and implanted the Vanguard Knee Implant with the Regenerex® 3-Peg Patella Implant in Ms. Lawson at the Dekalb Medical Center.

23.

Attached to the right is the sticker sheet related to that surgery and the medical devices that Dr. Traub inserted into Ms. Lawson on November 10, 2015:


Date: 11-10-15 Surgeon: Traub
Circulating Nurse: RN
Procedure: Right Total Knee
Scrub Nurse:
OR:
Device Implanted
FDA Designated Device Removed
Hip Bearing Surface
00.74 - metal/polyethelene
00.75 - metal/metal
00.76 - ceramic/ceramic
Phaco Time:
Please use check box for vendor supplied items.
Serial Number / Lot Number | Type of Device | Site | Quantity
BIOMET 194810 184736 — CC — 87.5 mm — Porous Plasma / Bond Coated — Right Knee — 1
BIOMET 141273 180160 — CC — T1 mm — With Locking Bar, Porous Titanium, Uncemented — 1
BIOMET 141314 843150 — CC — 40 mm — With Screw — 1
BIOMET 141356 870250 — 31 mm — DCR ArCam, Porous Titanium — V
Vendor:
DeKalb Medical
IMPLANT DOCUMENTATION AND TRACKING RECORD
Surgical Services
LAWSON, AUDREY LORRAINE
Jeff Traub
DOB 02/09/1971 F 11/10/2015 07:16
MRN 12060982 Acct2223053947

24.

Zimmer Biomet designed, manufactured, marketed, labeled, packaged, and/or sold the Vanguard Knee Implant with the Regenerex® 3-Peg Patella Implant that was implanted into Ms. Lawson.

25.

The initial post-operation x-rays of Ms. Lawson's right knee showed the Regenerex® 3-Peg Patella Implant to be well seated and in proper position.

26.

Following the surgery, Ms. Lawson's right knee pain improved, and she returned to her everyday activities.

27.

On or about March 22, 2017, the Zimmer Biomet Defendants issued a "Class 2 Device Recall" of the Regenerex® 3-Peg Patella Implant. The stated reason for the recall was due to the "pegs shearing post-operatively."

28.

In 2017, Ms. Lawson reported stiffness and pain coming from her patella after a fall. An x-ray was taken that did not show any loosening and further showed normal alignment.

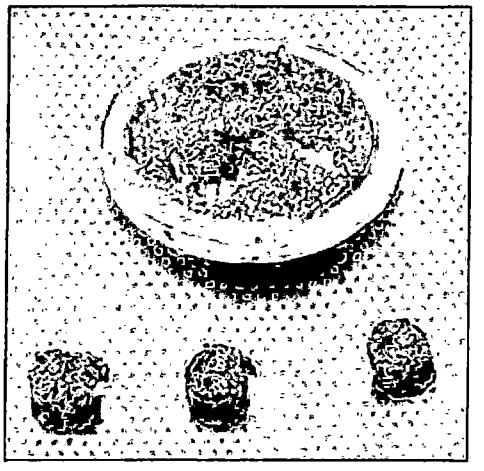
29.

On January 4, 2018, Ms. Lawson returned to Dr. Traub's office and continued to complain of pain in her right knee. Her knee was giving out and the steroid injections only provided temporary pain relief.

30.

On May 2, 2019, Dr. Traub noted that the Regenerex® 3-Peg Patella Implant that had been previously implanted in Ms. Lawson's right knee had failed.

Ms. Lawson's Failed Regenerex® 3-Peg Patella Implant



31.

On November 16, 2020, Dr. Traub performed a revision of Ms. Lawson's right knee to remove the failed Regenerex® 3-Peg Patella Implant. The Regenerex® 3-Peg Patella Implant failed because all three (3) of the Regenerex® pegs "sheared" off and became disassociated (or detached) from the circular polyethylene dome implanted in Ms. Lawson's knee (as you can see). So, Mr. Lawson's Regenerex® 3-Peg Patella Implant suffered from the same defect (shearing off of

pegs) that prompted the Defendants to issue the recall of the product.

32.

Despite being placed on antibiotics following the surgery, Ms. Lawson's wound from the revision surgery began to oozing, and her knee was painful and swollen. She continued to have weakness and a catching in her right knee. It was determined that once again her patella was not tracking right.

33.

On May 18, 2021, Dr. Christopher Harastzi performed surgery on Ms. Lawson. Specifically, Dr. Harastzi performed a right knee reconstruction of Ms. Lawson's dislocating patella with medial retinaculum and imbrication and lateral release.

34.

Ms. Lawson once again started to progress through physical therapy following the surgery. However, Ms. Lawson's right knee continued to ooze and drain from a hole that was approximately 3 mm in width for roughly six (6) weeks following the surgery.

35.

On July 6, 2021, Dr. Harastzi performed yet another surgery on Ms. Lawson's right knee. Dr. Harastzi performed a right knee incision and debridement due to suspected infection. She had a wound VAC placed on her knee as well.

36.

After her knee wound failed to close, Dr. Harastzi was able to obtain another culture of Ms. Lawson's knee drainage. This culture showed that Ms. Lawson had developed an infection in her knee joint. Bacterial infections can cling to the metal implant and hardware inside a

patient's body, making it difficult to kill. In order to treat the severe infection, Dr. Harastzi needed to remove her right knee hardware.

37.

On September 7, 2021, Dr. Harastzi surgically removed all of the previously implanted knee hardware in Ms. Lawson's right knee and replaced it with a concrete spacer that would leak antibiotics directly inside her knee. After this surgery, Ms. Lawson did not have a functioning knee and could not walk.

38.

After months of antibiotic treatment, Ms. Lawson was scheduled to have her right knee hardware reinserted. However, this surgery was delayed. On November 30, 2021, Ms. Lawson fell while trying to get up from her toilet due to the instability of her right knee. The fall fractured her right ankle. On December 8, 2021, Dr. Haraszti had to perform surgery on her right ankle and inserted hardware into her right ankle to fix this fracture.

39.

Ms. Lawson's right knee revision surgery to remove the concrete block and re-insert hardware has been delayed due to her ankle fracture. She was placed on bedrest for roughly three (3) months to allow her ankle to heal.

40.

The failure of the Regenerex® 3-Peg Patella Implant caused the need for multiple revision surgeries and caused Ms. Lawson to contract a Staphylococcal infection in her right knee. Since she had to have a concrete pacer put into her knee, she was particularly unstable and this caused her to fall and fracture her right ankle.

41.

As a direct and proximate result of the premature failure of the Regenerex® 3-Peg Patella Implant, Ms. Lawson has experienced and will continue to experience significant mental and physical pain and suffering, has sustained permanent injury to her right knee and bone loss, has undergone multiple surgeries, has suffered financial and economic loss, including, but no limited to, lost wages and obligations for medical services and expenses.

COUNT I:

PRODUCTS LIABILITY CLAIM

42.

Plaintiff incorporates by reference all of the preceding paragraphs of the Complaint as though fully set forth herein.

43.

Defendant was, at all relevant times, engaged in the business of designing, creating, manufacturing, testing, labeling, packaging, supplying, marketing, selling, advertising, warning and otherwise distributing and placing in the stream of commerce the Regenerex® 3-Peg Patella Implant.

44.

Defendant as the manufacturer, marketer, distributor, and seller of the Regenerex® 3-Peg Patella Implant is held to the level of knowledge of an expert in the field.

45.

Defendant knew or should have known that the Regenerex® 3-Peg Patella Implant was unsafe and defectively-designed for consumers using said implant in a reasonably foreseeable

manner in that the Regenerex® 3-Peg Patella Implant posed an unreasonably high risk of serious injury to consumers at the time of its design, manufacture, and sale.

46.

Specifically, the Regenerex® 3-Peg Patella Implant was defectively designed and/or manufactured because the Regenerex® pegs are porous, weak, and can break off and become disassociated (or detached) from the circular polyethylene dome while implanted in patients when being used in the manner for which it was intended considering its nature and intended function or for reasonably foreseeable uses.

47.

The Regenerex® 3-Peg Patella Implant was new when implanted into Ms. Lawson.

48.

The Regenerex® 3-Peg Patella Implant failed once placed inside Ms. Lawson's body as a result of the defective design by Defendant.

49.

As a direct and proximate cause of Defendant's defective design of the Regenerex® 3-Peg Patella Implant, Ms. Lawson suffered and continues to suffer serious injuries and damages as set forth herein – including but not limited to pain and suffering, emotional distress, financial loss, and lost income.

50.

Defendant is strictly liable to Ms. Lawson for designing, manufacturing, marketing, labeling, packaging and selling a defective product pursuant to O.C.G.A. § 51-1-11.

COUNT II:

FAILURE TO WARN CLAIM

51.

Plaintiff incorporates by reference all of the preceding paragraphs of this Complaint as though fully set forth herein.

52.

The Regenerex® 3-Peg Patella Implant that was implanted in Ms. Lawson was not reasonably safe for its intended use and was defective as a matter of law, and Defendant failed to warn and instruct Ms. Lawson and Dr. Traub of said defects.

53.

As a direct and proximate cause of Defendant's failure to warn, Ms. Lawson suffered and continues to suffer serious injuries and damages as set forth herein – including but not limited to pain and suffering, emotional distress, financial loss, and lost income.

54.

Defendant is strictly liable to Ms. Lawson for designing, manufacturing, marketing, labeling, packaging, and selling a defective product pursuant to O.C.G.A. § 51-1-11.

COUNT III:

BREACH EXPRESS WARRANTY CLAIMS

55.

Plaintiff incorporates by reference all of the preceding paragraphs of this Complaint as though fully set forth herein.

56.

Defendant made assurances to Ms. Lawson (by and through oral and public statements

made by Defendant's authorized agents to physicians, medical patients, and the general public) that the Regenerex® 3-Peg Patella was safe, effective, reasonably fit, and proper for its intended use.

57.

Ms. Lawson chose to have the Regenerex® 3-Peg Patella for her right knee arthroplasty based upon Defendant's warranties and representations regarding the safety and fitness of said device.

58.

Ms. Lawson, individually and/or by and through her physicians (including, but not limited to Dr. Traub), reasonably relied upon Defendant's express warranties and guarantees that the Regenerex® 3-Peg Patella was safe, merchantable, and reasonably fit for its intended purposes.

59.

Defendant's representations concerning the Regenerex® 3-Peg Patella were false because it was unsafe, unmerchantable, and unfit for ordinary purposes of its intended use.

60.

Defendant's breach of its express warranties and representations resulted in an unreasonably dangerous and defective product being implanted in Ms. Lawson's body, placing her health and safety in jeopardy.

61.

As a direct and proximate cause of Defendant's breach of these warranties, Ms. Lawson suffered and continues to suffer serious injuries and damages as set forth herein – including but

not limited to pain and suffering, emotional distress, financial loss, and lost income.

COUNT IV:

BREACH IMPLIED WARRANTY CLAIM

62.

Plaintiff incorporates by reference all of the preceding paragraphs of this Complaint as though fully set forth herein.

63.

Defendant implicitly warranted that the Regenerex® 3-Peg Patella was merchantable, safe, and fit for its ordinary intended use.

64.

When the Regenerex® 3-Peg Patella was implanted in Ms. Lawson to treat her osteoarthritis, said device was being used for the ordinary purposes for which it was intended.

65.

Ms. Lawson, individually and/or by and through her physicians (including, but not limited to Dr. Traub), reasonably relied upon Defendant's implied warranty of merchantability that the Regenerex® 3-Peg Patella was fit for its intended purposes in consenting to having said device implanted in her body.

66.

Defendant's implied warranty concerning the Regenerex® 3-Peg Patella was false because it was unsafe, unmerchantable, and unfit for ordinary purposes of its intended use.

67.

Defendant's breach of its implied warranty of merchantability resulted an unreasonably dangerous and defective product being implanted in Ms. Lawson's body, placing her health and safety in jeopardy.

68.

As a direct and proximate cause of Defendant's breach of their implied warranty, Ms. Lawson suffered and continues to suffer serious injuries and damages as set forth herein – including but not limited to pain and suffering, emotional distress, financial loss, and lost income.

69.

Defendant's actions and decisions concerning the design, manufacturing, marketing, labeling, packaging, and selling the Regenerex® 3-Peg Patella show willful misconduct, malice, fraud, wantoness, oppression, or that entire want of care which would raise the presumption of conscious indifference to the consequences thus authorizing an award of punitive damages under O.C.G.A. § 51-12-5.1.

WHEREFORE, PLAINTIFFS PRAY for the following:

(A) issuance and service of summons and process in terms of law;

(B) that Plaintiff has a trial by jury; and that Plaintiff has a judgment against the Defendant in amount to be shown at trial, together with all costs of this action;

(C) that punitive damages be awarded to Plaintiff against Defendant in an amount to be determined by the enlightened conscious of the jury; and

(D) any other relief that this Court deems just.

RESPECTFULLY SUBMITTED THIS 3rd day of August 2023.

BY: _____

TIMOTHY K. HALL
State Bar No. 319319
ADAM M. COLLINS
State Bar No. 153117

Counsel for Plaintiffs

HALL & COLLINS INJURY LAW, LLC
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IN THE STATE COURT OF GWINNETT COUNTY
STATE OF GEORGIA

AUDREY LAWSON, Plaintiff, v. **BIOMET, INC.** d/b/a Zimmer Biomet, Defendant.	**CIVIL ACTION NO.** 23-C-05517-S7

PLAINTIFF'S FIRST INTERROGATORIES TO DEFENDANT BIOMET, INC.

COMES NOW, Audrey Lawson, Plaintiff in the above-captioned civil action, and serves the First Interrogatories to Defendant Biomet, Inc. as follows:

NOTE A: Defendant is required under O.C.G.A. § 9-11-33 to either individually or jointly answer the Interrogatories separately and fully in writing and under oath and to serve a copy of said answers upon counsel for Plaintiff within forty-five (45) days after service of the summons and complaint upon said Defendant.

NOTE B: In answering the interrogatories, Defendant must furnish all requested information, not subject to a valid objection, that is known by, possessed by, or available to such entity or any of its attorneys, officers, employees, investigators, consultants, representatives, or other agents.

NOTE C: The Interrogatories shall be deemed continuing and supplemental responses shall be required as set forth in O.C.G.A. § 9-11-26(e). A responding party is under a duty seasonably to supplement the responses with respect to any interrogatory directly addressed to (i) the identity and location of persons having knowledge of discoverable matters, and (ii) the identity of each person expected to be called as an expert witness at trial, the subject matter on

which the expert is expected to testify, and the substance of the testimony. In addition, the responding party is under a duty seasonably to amend a prior response after obtaining information upon the basis of which the responding party either (i) knows that the response was incorrect when made, or (ii) knows that the response, though correct when made, is no longer true, and the circumstances are such that a failure to amend the response is, in substance, a knowing concealment.

NOTE D: If the responding party is unable to fully answer any of these interrogatories, said party must answer to the fullest extent possible, specify the reason(s) for his inability to answer the remainder, and state whatever information, knowledge, or belief it has concerning the unanswered portion.

NOTE E: Each lettered or enumerated subpart of a numbered interrogatory is to be considered a separate interrogatory for the purposes of objection. The party must object separately to each subpart, and if he objects to less than all of the subparts of a numbered interrogatory, then he must answer the remaining subparts to the extent that it is not objectionable.

NOTE F: As used herein, terms in the singular shall include the plural and terms in the plural include the singular and terms in the masculine shall include the feminine and neuter.

NOTE G: TIME LIMITATIONS. Unless otherwise noted, the interrogatories ask for information from the beginning of the design phase of the **"Regenerex® 3-Peg Patella Implant (Series A Patella)"** to present.

NOTE H: DEFINITIONS. Whenever used in these Interrogatories, the following words shall have the meanings set forth below:

(a) The terms "**you**," "**your**" shall mean the party or parties to whom these interrogatories are directed, including but not limited to, all individuals and entities, attorneys, employees, agents, or anyone acting on said party's behalf.

(b) The term "**Defendant**" means the above-captioned Defendant Biomet, Inc. d/b/a Zimmer Biomet and includes any employees, independent contractors, consultants, officers, private investigators, employees, or other agents who are in a position of obtaining or may have obtained information for or on behalf of Defendant relevant to these discovery requests.

(c) The term "**identify**" means the following: (1) in regard to any particular person and/or entity, means provide the name, residence address, business address, residence telephone number, business telephone number, and current employer if applicable; (2) in regard to a statement, document, or other written material, means provide the name of the person whose statement was obtained, and name and address of the person or entity taking each such statement or preparing each such document, the date it was taken or prepared, and the name and address of each such person having possession, custody or control of the original or a copy thereof; (3) in regard to any lawsuit, workers' compensation claim, bankruptcy proceeding, claim for insurance benefits, or other proceeding shall mean state the person involved, given the style and number of the case, the nature of the litigation, the role you or related parties played, the court or administrative body before which the suit or claim was made.

(d) The term "**document**" shall mean: (1) every writing or record of every type and description that is or has been in your possession, control, or custody in the broadest sense permitted by the Georgia Civil Practice Act or of which you have knowledge, including but not limited to, letters, correspondence, all memoranda, evaluations, interoffice communications, agreements, contracts, journals, tapes, e-mail, computer files, hard disks, databases, backup

tapes, stenographic or hand-written notes, studies, publications, books, pamphlets, pictures (drawings and photographs), films, microfilms, voice recordings, maps, reports, surveys, minutes, statistical computations, invoices, checks, production orders, sales records, drawings, engineering designs, laboratory or test reports, records of meetings, newspaper articles, telegrams, faxes, and any other writing evidencing or reflecting facts relevant to the Plaintiff's claim; (2) every copy of the above-described documents where the original is not in your possession, custody or control; (3) every copy of each such document where such copy is not an identical copy of the original by virtue of any commentary or notation that does not appear on the original.

(e) The term "**statement(s)**" means any written, oral, recorded, or other form of a statement, any deposition transcript, any court deposition, transcript or statement; any other written version of what a person has said.

(f) The term "**entity(ies)**" shall mean all governmental bodies, sole proprietorships, associations, companies, partnerships, joint ventures, corporations, trusts, estates, or similar collective organizations.

(g) The term "**person(s)**" shall mean all individuals – including but limited to agents, attorneys, investigators, employees, private investigators, engineers, independent contractors, or other representatives.

(h) The term "**Regenerex® 3-Peg Patella Implant (Series A Patella)**" refers to the patella implant that is the subject of this complaint, which includes but is not limited to all patella products which were approved under 510(K) number K083782 and subject to a Class 2 Device

Recall under Recall Number Z-2068-2017 and Recall Event Identification Number 77094. This product may be referred to as the **"Regenerex Patella Implant."**

INTERROGATORIES

General Information

1.

Please identify all persons who prepared or aided in the preparation of your answers to Plaintiff's interrogatories and requests for production of documents in this case.

2.

Please identify any person who you contend:

(a) Has some knowledge of the facts or circumstances about why the '**Regenerex Patella Implant**' allegedly failed, as allegedly in Plaintiff's complaint;

(b) Has knowledge of any facts relevant to the damaged claimed by Plaintiff;

(c) Has knowledge relevant to any defenses or denials in Defendant's answer. For each person or entity identified herein, please provide a summary of the facts to which you contend each person or entity has knowledge.

3.

(a) Please identify any and all persons you expect to call as an expert witness in the trial of this case, and itemize the substance of the facts and opinions to which the expert is expected to testify; and,

(b) Please list the qualifications, technical experience, and educational backgrounds for each person identified in subsection (a).

4.

Have any statements been obtained from any person having relevant knowledge of the allegations set forth in the Complaint? If so, identify (a) each person giving each statement; (b)

whether each statement was oral or written; (c) identify each person taking said statement, and (d) the substance of each statement. (NOTE: If a work product objection is made, please identify the statement with enough detail to allow a court to determine if the objection is proper.)

Identity of Defendant

5.

Please identify any other person or entity that is not named as a Defendant but who is a proper party to this action, and if you identify any such person or entity, briefly explain how and why said person or entity should be a party.

6.

Please identify the entity who: (a) manufactured; (b) designed; (c) packaged and labeled; (d) marketed; (e) advertised, and/or (f) distributed, through sale or otherwise the "**Regenerex Patella Implant**" that is the subject of this Complaint.

7.

Please identify: (a) the date and place of manufacture; (b) the date sold or otherwise distributed; (c) the name and address of the person/entity who sold and distributed; and (d) the name and address of the person/entity who purchased the specific "**Regenerex Patella Implant**" that is the subject of this Complaint.

8.

For each entity identified in your responses to Interrogatories 5-7, please identify: (a) legal name; (b) date and state of incorporation or formation; (c) officers and directors; (d) principal place of business and/or primary address; (e) if said entity is a partnership or limited liability company, the identity and present residences of all partners/members; (f) types of services and/or goods provided; and, (g) the business history, structure, organization, and

relationships with other entities, including but not limited to any predecessor and successive entities.

Instructions for Use & Installation

9.

Did Defendant use or provide any documents, manuals, warnings, or similar writings discussing the intended uses, hazards, dangers, approved or non-approved activities, precautions restrictions, or general instructions for use of the "**Regenerex Patella Implant**"? If so, please identify these documents by title and/or common name. (NOTE: please include all modifications or changes made to the documents identified).

10.

Please identify any instructions (including any modifications) provided to treating surgeons with respect to the installation of the "**Regenerex Patella Implant**"?

11.

Please identify the person responsible for selling the "**Regenerex Patella Implant**" subject to this Complaint.

Design & Testing

12.

a. Please identify the persons (including but not limited to the officers, engineers, consultants, independent contractors, or employees) responsible for the design of the "**Regenerex Patella Implant.**" Please include (i) the employer of the person so identified herein at the time of the design, (ii) her or her current employer, and (iii) a short summary of job performed.

b. Whose idea was it to make the pegs porous?

13.

Please identify the persons (including but not limited to the officers, engineers, consultants, independent contractors, or employees) responsible for any and all testing performed on the **"Regenerex Patella Implant."** Please include (i) the employer of the person so identified herein at the time of the design, (ii) her or her current employer, and (iii) a short summary of job performed.

14.

Did you perform any testing or evaluations of the strength, durability, or functioning of the pegs on the **"Regenerex Patella Implant"**. If so, identity (a) what tests were performed, (b) the date said tests were performed, (c) who performed said tests, and (d) the results and conclusions of said tests.

15.

Please identify the persons (including but not limited to the officers, engineers, consultants, independent contractors, or employees) responsible for preparing the documents and evidence submitted or used to obtain Section 510(k) approval and clearance from the U.S. Food and Drug Administration for the **"Regenerex Patella Implant"**. Please include (i) the employers of the person so identified herein at the time, (ii) her or her current employer, and (iii) a short summary of job performed.

16.

Please identify the person(s) responsible for maintaining the design notes, design history file, or other similar documents that compose the design file for the **Regenerex Patella Implant.**

17.

Has the design of the **Regenerex Patella Implant** been revised, altered, or otherwise

changed from its inception until present?

If so, identify: (a) the person(s) involved; (b) the date the design change; (c) the structure revised, altered, or changed; and (d) the reason for the change.

Other Knee Implant Failures

18.

From the date of its inception to the present, please identify and itemize any and all incidents where anyone has claimed or alleged that the pegs on the **Regenerex Patella Implant** sheared off, fractured, broke or failed to perform as it was designed and intended after being implanted into a patient.

For each prior failure identified, please include the following: (a) the date and contact information for the persons/entities involved (including the claimant and attorneys); (b) whether a lawsuit was filed, the caption of the lawsuit, date of said proceeding, and the court in which it was filed; (c) how the implant is alleged to have failed, specifically including whether there was any allegation of a failure of the pegs; and (d) the status and the resolution of said claim.

19.

a. Please explain how claims identified in Interrogatory No. 18 above are reported to you and/or tracked by you.

b. Please identify the persons responsible for tracking and reporting these incidents.

20.

Please identify the persons (including but not limited to the officers, engineers, consultants, independent contractors, or employees) responsible for investigating and then reporting adverse complaints concerning the **Regenerex® 3-Peg Patella Implant** or any part thereof to the U.S. Food and Drug Administration or any other federal agency from April 4, 2009

to present.

Please include (i) the employer of the persons so identified herein at that time; (ii) his or her current employer, and (iii) a short summary of jobs performed.

The Recall of the Regenerex Patella

21.

Please identify the persons (including but not limited to the officers, engineers, consultants, independent contractors, or employees) who made the decision to issue the Class 2 Device Recall of the **Regenerex® 3-Peg Patella Implant** on or about March 22, 2017?

Please include (i) the employers of the persons so identified herein at that time; (ii) his or her current employer, and (iii) a short summary of jobs performed.

22.

Please identify and explain the reason(s) that the **Regenerex® 3-Peg Patella Implant** was subject to a Class 2 Device Recall on or about March 22, 2017?

23.

Was the Class 2 Device Recall of the **Regenerex® 3-Peg Patella Implant** on or about March 22, 2017 voluntarily undertaken?

24.

(a) Please explain how and what was done to make the treating physicians aware of the Class 2 Device Recall of the **Regenerex® 3-Peg Patella Implant** that occurred on or about March 22, 2017?

(b) Please explain how and what was done to make Dr. Jeff A. Traub aware of the Class 2 Device Recall of the **Regenerex® 3-Peg Patella Implant** that occurred on or about March 22, 2017?

Quality Control

25.

Please identify the persons (including but not limited to the officers, engineers, consultants, independent contractors, or employees) responsible for quality control performed on the **Regenerex® 3-Peg Patella Implant.**

Please include (i) the employer of the persons so identified herein at that time; (ii) his or her current employer, and (iii) a short summary of jobs performed.

26.

What were your quality control, manufacturing, and inspection procedures used in the manufacture of the **Regenerex® 3-Peg Patella Implant?** Please identify all persons or entities responsible or involved in the quality control, manufacturing, and inspection procedures.

27.

Please identify any documents, manuals or other writings (electronic or otherwise) that show the manufacturing tolerances for the Regenerex Patella Implant, and identify what types of tools or measuring systems are in place to confirm the products are within tolerance.

Miscellaneous

28.

(a) Identify the total number of **Regenerex® 3-Peg Patella Implants** sold by you, and the total number of known failures due to the pegs shearing off, fracturing, breaking or otherwise failing.

(b) Identify the total number of **Regenerex® 3-Peg Patella Implant(s)** sold in Georgia, and total number of these that experienced failures due to the pegs shearing off, fracturing, breaking or other peg failure failing.

29.

Identify the nature and extent of all liability insurance coverage of every kind available directly or indirectly to you to pay any judgment awarded in this action, and include the name or names of each insurance company and the applicable limits of liability insurance in effect for each entity and/or occurrence.

30.

Please identify any peer reviewed journals, articles, and documents evaluating the **Regenerex® 3-Peg Patella Implant.**

THIS 3rd day of August 2023

BY: _____

TIMOTHY K. HALL
State Bar No. 319319
ADAM M. COLLINS
State Bar No. 153117

Counsel for Plaintiffs

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IN THE STATE COURT OF GWINNETT COUNTY
STATE OF GEORGIA

AUDREY LAWSON, Plaintiff, v. **BIOMET, INC.** d/b/a Zimmer Biomet, Defendant.	**CIVIL ACTION NO.** 23-C-05517-S7

PLAINTIFF'S FIRST REQUEST FOR PRODUCTION DOCUMENTS TO DEFENDANT BIOMET, INC.

COMES NOW, Audrey Lawson, Plaintiff in the above-captioned civil action, and serves the First Request for Production of Defendants as follows:

NOTE A: Plaintiff's Notes and definitions that were stated in the Plaintiff's First Interrogatories to Defendant Biomet, Inc. are hereby adopted and incorporated herein.

REQUEST FOR PRODUCTION OF DOCUMENTS

1.

With respect to each expert witness who may provide testimony at the trial of this case, provide:

A. A copy of all documents, information and items of any kind produced **to** said expert;

B. A copy of all documents, information and items of any kind generated or produced **by** said expert;

C. A copy of the entire file of said expert;

D. A current résumé or curriculum vitae for said expert;

E. All billing records and work logs for said expert; and

F. Any documents showing the fee arrangement and/or billing requirements for any work performed by said expert relating to this case.

2.

Please produce a copy of any statements identified in Interrogatory Number 4 (statements from any person having relevant knowledge of the allegations set forth in pleading in the above captioned case).

3.

Please produce all documents that reflect or show:

(a) The date of incorporation or creation and the correct legal name of the named Defendant; and,

(b) The date of any sale or any name change of any Defendant, including the identity of the purchaser and the details of the name change.

4.

Please produce any documents or other evidence supporting your contention (if any) that any other person or entity that is not named as a defendant as a defendant should be a proper party defendant to this action.

5.

Please produce all product description manuals, handbooks, and other informative documents that describe in graphic and/or written form the proper assembly, operation, or use of the **Regenerex® 3-Peg Patella Implant**.

6.

Please produce any documents or recordings (audio or video) concerning marketing materials, commercials of any kind (tv, radio, internet, print, etc.) brochures, instructions, or

other writings that discuss the installation, uses, benefits, and risk of the **Regenerex® 3-Peg Patella Implant.**

7.

Please produce any documents concerning manuals, warnings, or writings discussing the intended usage or dangers or general instruction for use of the **Regenerex® 3-Peg Patella Implant.**

8.

Please produce any documents concerning instructions provided to surgeons for use of the **Regenerex® 3-Peg Patella Implant.**

9.

Please produce the full design file for the **Regenerex® 3-Peg Patella Implant,** which may include but is not limited to the product concept, the objective of the product, the experiments performed, the engineering specifications and drawings, the clinical testing, and the manufacturing guidelines.

10.

Please produce all documents containing detail drawings, all sub-assembly drawings, the final assembly drawings, and other engineering documents for the **Regenerex® 3-Peg Patella Implant.**

11.

Please produce all documents concerning any and all calculations, experimentation, analysis, conclusions, or other testing and results performed on the **Regenerex® 3-Peg Patella Implant, specifically including any tests on the durability, strength or performance of the pegs.**

12.

Please produce all documents created since the inception of the design of the **Regenerex® 3-Peg Patella Implant** that related to the strength, effectiveness, durability, or use of the pegs.

13.

Please produce all documents created since the inception of the design of the **Regenerex® 3-Peg Patella Implant** that relate to the advantages, benefits, disadvantages, or risks of the design said product, including the patella pegs. Please include all risk/benefit analysis documents.

14.

Please produce all documents that concern calculations, experimentation, analysis, or other testing and results on the amount of force needed to shear off, break, fracture or move in any manner the pegs on the **Regenerex® 3-Peg Patella Implant.**

15.

Please produce any and all documents showing the results of any testing or evaluations of the strength, durability, of functioning of the **Regenerex® 3-Peg Patella Implant,** especially concerning the three (3) pegs.

16.

Please produce all documents showing the results of any studies and/or clinical trials evaluating the safety and efficacy of the **Regenerex® 3-Peg Patella Implant.**

17.

Please produce a copy of any peer review journals, articles, or documents evaluating the the **Regenerex® 3-Peg Patella Implant.**

18.

Please produce all documents concerning the quality control, manufacturing, and inspection procedures used in the manufacture and assembly of the **Regenerex® 3-Peg Patella Implant.**

19.

Please produce all documents concerning or related to complaints, lawsuits, claims, mediations, or any other grievance from anyone concerning a failure of the **Regenerex® 3-Peg Patella Implant.**

20.

Please produce any documents related to any other patients who have suffered a failure of the **Regenerex® 3-Peg Patella Implant.**

21.

Please produce all documents or correspondence sent to or received from any federal agency, including the U.S. Food and Drug Administration, by any person or entity related to the **Regenerex® 3-Peg Patella Implant** or any part thereof, specifically including any request for 510(k) approval.

22.

Please produce all documents either relied on or created as part of obtaining 510(k) approval from federal agency, including the U.S. Food and Drug Administration, for the **Regenerex® 3-Peg Patella Implant** or any part thereof.

23.

Please produce all documents that reflect or concern the sale and purchase of the **Regenerex® 3-Peg Patella Implant** or any part thereof that was implanted in Plaintiff.

24.

(a) Please produce any document showing or reflecting the total sales of the **Regenerex® 3-Peg Patella Implant** from its inception to the recall.

(b) Please produce any document showing or reflecting all of the total sales in Georgia of the **Regenerex® 3-Peg Patella Implant** from its inception to the recall.

25.

Please produce any documents related to the recall, specifically including any correspondence sent to the generally public or the treating physicians concerning the recall.

26.

Please produce any documents or correspondence sent to Dr. Jeff A. Traub or his offices, specifically including any documents or correspondence concerning the Class 2 Device Recall of the **Regenerex® 3-Peg Patella Implant** that occurred on or about March 22, 2017.

27.

Please produce all documents showing the results of any investigation or reports of adverse complaints concerning the **Regenerex® 3-Peg Patella Implant** or any part thereof to the U.S. Food and Drug Administration or any other federal agency.

28.

Please produce all documents concerning the recall of the **Regenerex® 3-Peg Patella Implant.**

29.

Please produce a copy of any declarations page for any insurance coverages that may be applicable to this claim.

30.

Please produce the entire claim file related to Plaintiff's claim.

31.

Please produce any document related to any patents, license, and/or trademarks related to the **Regenerex® 3-Peg Patella Implant.**

32.

Please produce any documents relied on to respond to Plaintiff's interrogatories.

THIS 31st day of August 2023.

BY: _____

TIMOTHY K. HALL
State Bar No. 319319
ADAM M. COLLINS
State Bar No. 153117

Counsel for Plaintiffs

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